POLICY AND PROCEDURES

OFFICE OF GENERIC DRUGS

Criteria and Procedures for Managing the Review of Original ANDAs, Amendments and Supplements

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PURPOSE

 This MAPP describes the criteria and procedures by which the Office of Generic Drugs (OGD), Division of Project Management leadership will manage the review of generic drug submissions.

BACKGROUND

- Concurrent with the issuance of this MAPP, OGD issued MAPP 5240.3 Rev.1, *Prioritization of the Review of Original ANDAs, Amendments and Supplements.*
- MAPP 5240.3 Rev.1 identifies categories of submissions that are public health priorities, including submissions containing patent certifications pursuant to 21 CFR 314.94(a)(12) (some of which are "potential first generic products"); submissions related to drug shortages; and submissions that are subject to special review programs such as the President's Emergency Plan for AIDS Relief.
- Industry, consumers and other stakeholders have a strong interest in the predictable and timely review of public health priority submissions. Expediting the review of such submissions is a key aim of the Generic Drug User Fee Amendments of 2012 (GDUFA).

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- The GDUFA Commitment Letter also establishes metrics (goal dates) for various categories of generic drug submissions, including ANDAs submitted in Fiscal Years 2015, 2016 and 2017.
- Transparency is another key aim of GDUFA. As OGD changes its policies and
 procedures to achieve GDUFA metric goals, stakeholders have a strong interest in
 transparency concerning the review of public health priority submissions. Industry
 has an especially strong interest in transparency concerning the review of their
 potential first generic products.
- To promote transparency, this MAPP describes the criteria and procedures by which OGD Division of Project Management leadership will manage the review of generic drug submissions by the various technical review disciplines (chemistry, bioequivalence, etc.).

POLICY

- OGD Division of Project Management leadership will manage the review of generic drug submissions based on three criteria: (1) GDUFA metric goals, (2) public health priorities, and (3) review capacity across disciplines.
 - 1) Submissions with GDUFA metric goals will be given review timeframes designed to achieve GDUFA metric goals. The Agency is committed to meet the GDUFA metric goals.
 - 2) Submissions that are public health priorities may be granted expedited review in order to achieve public health goals as set forth in MAPP 5240.3 Rev.1, *Prioritization of the Review of Original ANDAs, Amendments and Supplements*.
 - a) If a submission is a public health priority and has no GDUFA metric goal, the submission may be expedited as necessary to address the public health need.
 - b) If a submission is a public health priority and does have a GDUFA metric goal, it may be expedited by designating the goal of action in advance of the metric goal.
 - 3) In managing the review of generic drug submissions, OGD Division of Project Management staff will consider workload management issues, such as the capacity of the review disciplines and the distribution of work among them at any given time.

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RESPONSIBILITIES

- OGD Division of Project Management leadership, supervised by the OGD Office
 of Operations Director, will have overall responsibility for applying the criteria
 and carrying out the procedures set forth in this MAPP.
- Review Discipline leadership will be responsible for monitoring and reporting their review capacity to OGD Division of Project Management leadership and the OGD Director's Immediate Office.

PROCEDURES

- On an ongoing basis, OGD Division of Project Management leadership will survey OGD's inventory of submissions pending review and the capacity of the review disciplines.
- Bimonthly, OGD Division of Project Management leadership will consult with Review Discipline leadership, then meet with Office of Pharmaceutical Science operations leadership to identify the next group of submissions for review based on the criteria set forth in this MAPP.
- On the basis of new information that might affect the prioritization of a submission, such as the impending expiration of a blocking patent or the favorable conclusion of patent litigation, OGD Division of Project Management leadership may adjust the group of submissions under review.

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EFFECTIVE DATE

This MAPP is effective upon issuance, and applies to all generic drug submissions, including those pending with the Agency as of that date, unless otherwise noted.

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¹ Applicants may advise OGD Regulatory Project Managers of information that might affect the prioritization of a submission. See MAPP 5200.3 Rev.1, Responding to Industry Inquiries with Respect to Abbreviated New Drug Applications in the Office of Generic Drugs.

MANUAL OF POLICIES AND PROCEDURES

CENTER FOR DRUG EVALUATION AND RESEARCH

MAPP 5200.4

CHANGE CONTROL TABLE

Effective	Revision	Revisions
Date	Number	

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